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REMARKS

Claims 18-24 are pending in the application. Claims 1-17 are withdrawn from consideration as being drawn to non-elected inventions. Applicants expressly reserve the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the remaining claims. Claims 18, 21, 23 and 24 (and thus dependent claims 19, 20 and 22) have been amended. Support for the amendments can be found in the specification as filed. No new matter has been added by way of amendment. Reexamination and reconsideration of the claims are respectfully requested.

Deposit Numbers

On page 2 of the Office Action mailed February 26, 2003, the Examiner states that the disclosure is objected to because deposit numbers are missing from page 4, lines 15 and 17, page 5, line 17 and page 6, line 16. Applicants have amended the specification to remove reference to the ATCC deposit numbers, thereby obviating the objection.

Hyperlinks

The Examiner has objected to the disclosure due to the inclusion of a hyperlink on page 16, line 31. Applicants have amended the specification to remove the hyperlink, thereby obviating the objection.

Replacement Paragraphs

The Examiner has indicated that several lines of the specification are faint and difficult to read, and has suggested that Applicants submit replacement paragraphs. Applicant has included all the paragraphs suggested by the Examiner in the previous section of amendments to the specification. No amendments have been made to the paragraphs in question.

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Title

The Examiner has objected to the title of the invention as not being descriptive of the instant invention. Applicants have amended the title to "Maize Proteinase Inhibitor-Like Polynucleotides and Defense-Activated Promoter, Transformed Plants, and Methods of Use", in order to more clearly indicate the invention to which the claims are directed. This amendment is shown in the previous section entitled "Amendments to the Specification", beginning on page 2 of the instant response. No new matter is added by way of the amendment to the title.

Abstract

The Examiner has objected to the abstract of the invention as not being descriptive of the instant invention. Applicants have amended the abstract as shown in the previous section entitled "Amendments to the Specification", beginning on page 2 of the instant response. Applicants assert that the new abstract is clearly indicative of the invention to which the claims are directed. No new matter is added by way of the amendment to the abstract.

Claim Objections

The Examiner has objected to claims 23 and 24 because of informalities. The Examiner has further provided suggested amendments to overcome these informalities. Applicants have amended claims 23 and 24 according to the Examiner's suggestions, thereby obviating the claim objections.

The Rejection of Claims Under 35 U.S.C. §112, First Paragraph, Should be Withdrawn
Enablement

The Examiner has rejected claims 18-24 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully disagree.

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The Examiner states that the instant specification fails to provide guidance for how the proteinase inhibitor-like DNA sequence and its promoter were isolated. Applicants have provided the full-length sequence for both the proteinase inhibitor-like gene and its promoter in the sequence listing submitted with the specification as originally filed. Clearly, given the sequences of the gene and its promoter, anyone of skill in the art would be enabled to make and use the gene and its promoter. This could be accomplished by complete synthesis of the gene and promoter themselves, or by the use of primers to isolate the genes from maize DNA. Such techniques are well known by those of skill in the art.

The Examiner further states that the instant specification fails to provide guidance for exact hybridization or amplification conditions and probes/primers to use in isolation of promoters other than SEQ ID NO: 3. Applicants respectfully disagree. Applicants have provided extensive guidance to be used in the selection of stringency conditions based on the desired outcome. See page 13, line 13 through page 14, line 4 of the specification as originally filed. Applicants have also provided an extensive discussion of hybridization conditions and requirements from page 14, line 5 through page 15, line 3. The design of appropriate primers has been outlined by the Applicants on page 7, line 19 through page 8, line 4 and further on page 12, lines 8-19. Furthermore, Applicants have given guidance regarding the design and use of probes on page 12, line 20 through page 13, line 12. In view of the extensive guidance provided, Applicants assert that the invention is clearly enabled as claimed. However, in order to further prosecution, Applicants have amended claims 18 and 21 to remove reference to promoters comprising 20 contiguous nucleotides of SEQ ID NO: 3. Applicants have also amended claims 18 and 21 to recite 95% identity to SEQ ID NO:3.

Written Description

The Examiner has rejected claims 18-24 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

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The Examiner states that the Applicants have not, in fact, described DNA molecules that are promoters that have 75% identity to SEQ ID NO:3 or that comprise 20 contiguous nucleotides of SEQ ID NO:3, and the specification fails to provide an adequate written description of the invention. Applicants respectfully disagree. In view of the claim amendments previously discussed, promoters that comprise 20 contiguous nucleotides of SEQ ID NO:3 are no longer being claimed. Furthermore, Applicants have amended the claims to recite promoters that have 95% identity to SEQ ID NO:3.

The recitation of at least 95% sequence identity is a *very predictable structure* of the sequences encompassed by the claimed invention. Applicants note that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. 66 Fed. Reg. 1099, 1106 (2001). Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. *Id.* Applicants submit that the knowledge and level of skill in the art would allow a person of ordinary skill to envision the claimed invention, *i.e.*, a nucleotide sequence having at least 95% sequence identity to SEQ ID NO:3, which also is capable of regulating transcription.

Furthermore, the description of a claimed genus can be by structure, formula, chemical name, or physical properties. *See, Ex parte Maizel*, 27 USPQ2d 1662, 1669 (B.P.A.I. 1992), citing *Amgen v. Chugai*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). A genus of DNAs may therefore be described by means of a recitation of a representative number of DNAs defined by nucleotide sequence and falling within the scope of the genus, *or* by means of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *See, Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997); *see also* Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, First Paragraph, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (2001). The recitation

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of a predictable structure of at least 95% sequence identity to SEQ ID NO:3 is sufficient to satisfy the written description requirement for the nucleotide sequence element of the claims.

An Applicant, however, may also rely upon functional characteristics in the description, provided there is a correlation between the function and structure of the claimed invention. *See id.*, citing *Lilly* at 1568. Here, claims 18 and 21 recite functional characteristics of the claimed genus, specifically requiring that the nucleotide sequence is capable of regulating transcription, thereby providing a functional characterization of the sequences claimed in the genus.

Applicants bring to the attention of the Examiner Example 14 of the Revised Interim Written Description Guidelines, which is directed to a generic claim: a protein having at least 95% sequence identity to the sequence of SEQ ID NO:3, wherin the sequence catalyzes the reaction A → B. The Training Materials concludes that the generic claim of Example 14 is sufficiently described under §112, first paragraph, because: 1) "the single sequence disclosed in SEQ ID NO:3 is representative of the genus"; and 2) the claim recites a limitation requiring the compound to catalyze the reaction from A → B. The Guidelines conclude that one of skill in art would recognize that the Applicants were in possession of the necessary common attributes possessed by the members of the genus.

Following the analysis of Example 14, Applicants submit that the present claims satisfy the written description requirements of § 112, first paragraph. Specifically, the claims of the present invention encompass nucleotide sequences having at least 95% sequence identity to SEQ ID NO:3, wherin said nucleotide sequences also are capable of regulating transcription. As in Example 14, the specification discloses the nucleic acid sequence of SEQ ID NO:3 and claims 18 and 21 (and thus their respective dependent claims) recite a limitation requiring the nucleotide sequence to have a specific function (*i.e.*, capable of regulating transcription). Consequently, contrary to the conclusion in the Office Action, the sequences encompassed by claims 18 and 21, and their respective dependent claims, are defined by relevant identifying physical and chemical properties.

In summary, the description of a representative number of species *does not* require the description to be of such specificity that it would provide individual support for each species that

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the genus embraces. Applicants submit that the relevant identifying physical and chemical properties of the disclosed genus would be clearly recognized by one of skill in the art and consequently, the Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus.

Accordingly, Applicants respectfully request the withdrawal of the rejection of claims 18-24 under 35 U.S.C. §112, first paragraph.

The Rejection of Claims Under 35 U.S.C. §112, Second Paragraph, Should be Withdrawn

The Examiner has rejected claims 18-24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Applicants have amended claims 18 and 21 to remove reference to "20 contiguous nucleotide sequences", thereby obviating the rejection as it applies to these claims.

Applicants have amended claim 21 to correct the antecedent basis by removing the term "heterologous" since this limitation is recited earlier in the claim.

Accordingly, Applicants respectfully request withdrawal of the rejections of claims 18-24 under 35 U.S.C. §112, second paragraph.

The Rejection of Claims Under 35 U.S.C. §102 Should be Withdrawn

The Examiner has rejected claims 18-24 under 35 U.S.C. 102(e) as being anticipated by Perera *et al.* (US Patent 6,462,257). Perera *et al.* teach a promoter from pinc that comprises 36 contiguous nucleotides of SEQ ID NO:3. Perera *et al.* do not teach, disclose or suggest a proteinase inhibitor-like gene or its promoter, nor do they teach, disclose or suggest the sequence set forth in SEQ ID NO:3. Accordingly, in view of the claim amendments removing reference to promoters comprising 20 contiguous nucleotides of SEQ ID NO: 3, Applicants assert that the Perera *et al.* reference does not apply as 35 U.S.C. 102(e) art to the amended claims.

In view of the preceding remarks and claim amendments, Applicants respectfully request withdrawal of the rejection of the claims under 35 U.S.C. §102.

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CONCLUSION

In view of the above amendments and remarks, Applicants submit that the rejections of the claims under 35 U.S.C. §§112, first and second paragraphs and 35 U.S.C. § 102 have been overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-1852.

Respectfully submitted,

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